ATTORNEY'S DOCKET NUMBER ORM PTO 1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE REV. 12-2004) TPP31757 TRANSMITTAL LETTER TO THE UNITED STATES U.S. APPLICATION NO. (If known, see 37 CFR 1.5) DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY 29 AUGUST 2002 PCT/GB2003/003751 29 AUGUST 2003 TITLE OF INVENTION PHARMACEUTICAL PRODUCTS AND COMPOSITIONS COMPRISING SPECIFIC ANTICHOLINERGIC AGENTS, BETA-2 AGONISTS AND CORTICOSTEROIDS APPLICANT(S) FOR DO/EO/US L'ULLA, Amar MALHOTRA, Geena Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 1. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 2. \boxtimes This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), 3. (9) and (24) indicated below. \boxtimes The US has been elected (Article 31). 4. A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) is attached hereto (required only if not communicated by the International Bureau). a. 🗆 b. \boxtimes has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). 6. a. 🗆 is attached hereto. b. 🗆 has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)) 7. \boxtimes are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. b. have not been made; however, the time limit for making such amendments has NOT expired. c. d. ⊠ have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 8. An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). 9. An English language translation of the annexes to the International Preliminary Examination Report under PCT 19 Article 36 (35 U.S.C. 371 (c)(5)). \boxtimes A copy of the International Preliminary Examination Report (PCT/IPEA/409). 12. 冈 A copy of the International Search Report (PCT/ISA/210). Items 13 to 23 below concern document(s) or information included: 13. An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 14. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 15. \boxtimes A FIRST preliminary amendment. A SECOND or SUBSEQUENT preliminary amendment. 16. 17. A substitute specification. A power of attorney and/or change of address letter. 18. 19. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. A second copy of the published International Application under 35 U.S.C. 154(d)(4). 20. 21. A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4). 22. Express Mail Label No. \boxtimes 23. Other items or information: a. Copy of application as published (WO 2004/019985) b. PCT/RO/101 (REQUEST) c. PCT/IPEA/416 d. Notice of Claim for Priority

PTO-1390 (Rev. 12-2004)
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U.S. APPLICATION NO (if known, see 37 CFR 1.5) INTERNATIONAL APPLICATION NO. ATTORNEY'S DOCKET NUMBER PCT/GB2003/003751 TPP31757 24. The following fees are submitted: Applicant use Office use \$300.00 \$300.00 \boxtimes \$200.00 \$200.00 c) Search fee \$500.00 \$500.00 TOTAL OF ABOVE CALCULATIONS = \$1000.00 \$1,000.00 Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. **Total Sheets** Number of each additional 50 or Extra Sheets fraction thereof (round up to a whole -100 =/50 = \$250.00 \$0.00 Surcharge of \$130.00 for furnishing the oath or declaration later than months from the \$ earliest claimed priority date (37 CFR 1.492(e)). NUMBER FILED NUMBER EXTRA RATE Total claims 33 - 20 = 13 \$50.00 \$650.00 Independent claims 0 x \$200.00 \$0.00 MULTIPLE DEPENDENT CLAIMS (if applicable) \$360.00 \$0.00 TOTAL OF ABOVE CALCULATIONS = \$1,650.00 Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are \$0.00 reduced by 1/2. SUBTOTAL = \$1,650.00 Processing fee of \$130.00 for furnishing the English translation later than 30 months from \$0.00 the earliest claimed priority date (37 CFR 1.492(f)). \$1,650.00 TOTAL NATIONAL FEE = Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property \$0.00 TOTAL FEES ENCLOSED = \$1,650.00 Amount to be refunded: Amount to be charged: a. A check in the amount of \$ \$1,650.00 to cover the above fees is enclosed. Please charge my Deposit Account No. b. 🔲 in the amount of to cover the above fees. A duplicate copy of this sheet is The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment 19-4375 . A duplicate copy of this sheet is enclosed. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. SEND ALL CORRESPONDENCE TO: Thomas P. Pavelko, Esquire SIGNATURE STEVENS, DAVIS, MILLER & MOSHER, L.L.P. Thomas P. Pavelko 1615 L Street, N.W., Suite 850 Washington, D.C. 20036 NAME Telephone: (202) 785-0100 31,689 Facsimile: (202) 408-5200 or (202) 408-5088 **REGISTRATION NUMBER**

Page 2 of 2

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THE APPLICANT HEREWITH PETITIONS THE PTO TO EXTEND THE TIME FOR RESPONSE AS REQUIRED TO MAKE THE ATTACHED DOCUMENT TIMELY FILED. PLEASE CHARGE THE COST THEREOF TO DEPOSIT ACCOUNT 19-4375